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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,111	11/20/2000	Christopher Marriott	REF/MARIOTT/	3979

7590

04/16/2003

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/16/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,111	MARRIOTT ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Notice of Appeal filed 12/12/02, Request for Extension of Time, Request for Continued Examination, and Preliminary Amendment filed 02/26/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/26/03 has been entered.

Response to Amendment

In the Amendment filed on 02/26/03, applicant requested to cancel claims 1-5, 7-10, 12, 13, 19, and added claims 25-41. However, in the remarks, page 5 stated "applicants have canceled all the claims from the application without prejudice or disclaimer and new claims 25-41 have been added". Applicant has not mentioned claims, which previously been withdrawn or objected, including, claims 6, 11, 14-17, and 20-24. Further clarification is suggested. It appears that newly added claims include the subject matters of claims s, which previously been withdrawn or objected, including,

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claims. For the purpose of searching and examining, the claims have not been further treated on merits until further clarification is submitted.

Claim Objections

Claim 39 is objected to because of the following informalities:

It appears that the word "ration" in line 3 should read "ratio". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-27, 29-31, 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. US 4,725,387, in view of Trofast et al. WO 95/05805.

Hirao teaches a process of shaping crystals of sugar alcohols by obtaining a saccharified starch solution with high maltose content, allowing crystallization, and separating the crystallized solid (column 2, lines 38 through column 3, lines 1-11). The viscosity of the solution can be regulated by the addition of water-soluble organic solvent, or elevated temperature (column 4, lines 45-68; and example 1). Hirao does not teach the viscosity of less than 25 Pa.s at a shear rate of $1s^{-1}$. However, no criticality is seen in the particular viscosity since Hirao obtains the same result desired

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by the applicant, e.g., a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape (column 7, lines 33-53). Accordingly, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable viscosity of the solution to obtain the claimed invention.

Hirao does not teach the solid crystals can be used for inhalation. However, Hirao in column 5, lines 20-58 teaches besides anhydrous crystals of maltitol, *other sugar alcohols such as sorbitol, maltotriitol and maltotetraitol* can be used for various uses, e.g., for foods, cosmetics, and *drugs*. Hirao further teaches that maltitol or crystalline mixture solid can be prepared into desirable shape, including granule with a granulizer (column 7, lines 66 through column 8, lines 1-4).

Trofast teaches a stable crystallinic form of fine-grained substance or substance mixture useful for inhalation (page 4, lines 23-30). The substance includes salbutamol sulfate, ipratropium bromide, or salmeterol xinafoate (page 7, lines 26 through page 8, lines 1-3). The substance may be combined with carriers suitable for inhalation, such as lactose, maltose, maltitol, starch, and its hydrates (page 6, lines 21-31). Thus, it would have been obvious for one of ordinary skill in the art to optimize the solid crystalline mixture of Hirao as a carrier useful for inhalation of pharmaceutical formulation in view of the teachings of Trofast, because the references teach the advantageous result in the use of carrier, such as maltitol and lactose monohydrate as a carrier for inhalation formulation.

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Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. in view of Trofast et al., and Douglas et al. US 5,635,200.

Hirao and Trofast are relied upon for the reasons stated above. The references are silent as to the teaching of carbomer as a starch or binder in an aqueous solution. However, carbomer is a well known starch or thickener, or binder in pharmaceutical art. Douglas teaches an oral administration composition comprising starch or carbopol as an aqueous solution thickener (column 7, lines 22-32). Hence, it would have been obvious for one of ordinary skill in the art to modify Hirao's starch solution using carbopol taught by Douglas. The unexpected result is free flowing crystal having desire size and shape.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al., in view of Staniforth WO 96/23485.

Hirao is relied upon for the reasons stated above. Hirao does not teach the size range of the crystallized solid.

Staniforth teaches carrier particles useful in dry powder inhalers comprising one or more crystalline sugars including lactose, having particles diameter between from 60 μm to 180 μm (page 10, lines 2-17). Thus, it would have been obvious for one of ordinary skill in this art to modify Hirao crystalline solid carrier to have the particle size suitable for inhalation in view of the teachings of Staniforth, because the references teach the advantageous result in the use of crystalline sugars in pharmaceutical art. The unexpected result is a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape.

R sponse to Arguments

Applicant's arguments filed 02/26/03 have been fully considered but they are not persuasive.

Applicant argues that Hirao is clearly related to the solving of a very specific problem associated with maltitol in foodstuffs, i.e., a different technical field to the current invention, and therefore, a person skilled in the art would not consider maltitol for use in an inhalation product. Applicant further support his assertion by showing abstract from the Handbook of Pharmaceutical Excipients, noted that maltitol is only known in the pharmaceutical art as bulk sweetener for oral dosage forms. Contrary to the applicant's argument, Trofast in page 6, lines 21-31 discloses useful carrier for inhalation dosage form, including, carbohydrates like lactose, maltitol, and its hydrates. Hirao in column 5, lines 20-58 teaches besides anhydrous crystals of maltitol, *other sugar alcohols such as sorbitol, maltotriitol and maltotetraitol* can be used for various uses, e.g., for foods, cosmetics, and *drugs*. Hirao further teaches that maltitol *or* crystalline mixture solid can be prepared into desirable shape, including granule with a granulizer (column 7, lines 66 through column 8, lines 1-4). Accordingly, a person skilled in the art would consider maltitol for use in an inhalation product, and would optimize the teachings of Hirao in view of the teachings of Trofast to obtain the claimed invention.


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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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